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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,798	11/26/2003	Ajit Lalvani	117-485	6314

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NIXON & VANDERHYE, PC
1100 N GLEBE ROAD
8TH FLOOR
ARLINGTON, VA 22201-4714

EXAMINER	
SWARTZ, RODNEY P	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/721,798	LALVANI ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-27 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12 and 14-18, drawn to method of identifying CD8 T-cells using polypeptide and a kit, classified in class 436, subclass 501.

II. Claims 13 and 19, drawn to method of identifying CD8 T-cells using DNA and a kit, classified in class 435, subclass 69.1.

III. Claims 20, 21, 26, and 27, drawn to polypeptide composition, classified in class 424, subclass 248.1.

IV. Claims 22-25, drawn to method of vaccination using polypeptide, classified in class 424, subclass 9.2.

V. Claims 22-25, drawn to gene therapy, classified in class 514, subclass 44.

VI. Claims 26 and 27, drawn to DNA composition, classified in class 536, subclass 23.7.

Claims 22-27 are drawn to multiple, distinct inventions.

Claims 22-25 are drawn to a method of vaccination using polypeptides **or** a method of gene therapy using nucleic acids. Claims 26 and 27 are drawn to a composition of polypeptides **or** nucleic acids. Therefore, claims 22-27 have been included into multiple inventions where appropriate. However, election of **a single** invention which includes either claim 22, 23, 24, 25, 26, or 27 necessitates that claim 22, 23, 24, 25, 26, or 27 is directed **only** to the elected invention, i.e, polypeptides or nucleic acids. Appropriate correction of claim 22, 23, 24, 25, 26, or 27 is required upon election to **recite only the elected invention**.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are drawn to structurally and functionally distinct products. Invention I is drawn to polypeptides while Invention II is drawn to nucleic acids.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of Invention III can be utilized for immunization of subjects against *M. tuberculosis*.

Inventions I and IV are drawn to distinct methods utilizing different procedural steps resulting in different objectives.

Inventions I and V are drawn to structurally and functionally distinct products. Invention I is drawn to polypeptides while Invention V is drawn to nucleic acids.

Inventions I and VI are drawn to structurally and functionally distinct products. Invention I is drawn to polypeptides while Invention V is drawn to nucleic acids.

Inventions II and III are drawn to structurally and functionally distinct products. Invention III is drawn to polypeptides while Invention II is drawn to nucleic acids.

Inventions II and IV are drawn to structurally and functionally distinct products. Invention IV is drawn to polypeptides while Invention II is drawn to nucleic acids.

Inventions II and V are drawn to distinct methods utilizing different procedural steps resulting in different objectives.

Inventions II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the

product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the DNA of Invention VI can be utilized for gene therapy for immunization of subjects against *M. tuberculosis*.

Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of Invention III can be utilized *in vitro* for diagnosis of infection with *M. tuberculosis*.

Inventions III and V are drawn to structurally and functionally distinct products. Invention III is drawn to polypeptides while Invention V is drawn to nucleic acids.

Inventions III and VI are drawn to structurally and functionally distinct products. Invention III is drawn to polypeptides while Invention VI is drawn to nucleic acids.

Inventions IV and V are drawn to structurally and functionally distinct products. Invention IV is drawn to polypeptides while Invention V is drawn to nucleic acids.

Inventions IV and VI are drawn to structurally and functionally distinct products. Invention IV is drawn to polypeptides while Invention VI is drawn to nucleic acids.

Inventions V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the DNA of Invention V can be utilized *in vitro* for diagnosis of infection with *M. tuberculosis* using hybridization techniques.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and because while the searches may overlap, the searches are not coextensive, restriction for examination purposes as indicated is proper.

2. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

September 1, 2004